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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/983,069	10/23/2001	Kiyohito Ishida	ISHIDA=8A	8892

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EXAMINER

IP, SIKYIN

ART UNIT	PAPER NUMBER
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1742

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

<b>Office Action Summary</b>	<b>Application No.</b> 09/983,069	<b>Applicant(s)</b> ISHIDA ET AL.	
	<b>Examiner</b> Sikyin Ip	<b>Art Unit</b> 1742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 January 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,5-7,10-12 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5-7, 10-12, 14-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

Claims 1 and 5-6 are objected to because of the following informalities: In claim 1, line 17, the wording "boyd" is an apparent typographical error. Appropriate correction is required.

### ***Double Patenting***

Double patenting rejection has been withdrawn in view of instant remarks.

## **Claim Rejections - 35 USC § 103**

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-7, 10-12, and 14-17 are rejected under 35 U.S.C. § 103 as being unpatentable over USP 5769796 to Palermo et al in view of USP 4750953 to Tabei.

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Palermo in col. 1, line 60 to col. 2, line 30 discloses a multi-section guidewire having a body portion relatively high in rigidity and a distal portion relatively flexible which reads on stepwise changing from high-rigidity to low-rigidity tip end portion. The conventional catheter guidewire is tapered along its length to allow great flexibility (Palermo, col. 1, lines 60-67 and col. 5, lines 20-27). The coil could be plated or coated with a malleable or solderable metal such as gold (Palermo, col. 4, lines 6-25 and col. 6, lines 1-15). The guidewire material is selected from stainless steel wire, super-elastic alloy tubing, or braid of a super-elastic alloy ribbon (Palermo, col 4, lines 26-39). The difference between the reference(s) and the claims are as follows: Palermo does not disclose the claimed specific shape memory/super-elastic Cu-Al-Mn alloy and its heat treatment steps. But, the invention defined in a product-by-process claim is a product, not a process. In re Bridgeford, 357 F. 2d 679, 149 USPQ 55 (CCPA 1966) and MPEP § 2113. It is the patentability of the product claimed and not of the recited process steps which must be established. See In re Brown, 459 F. 2d 531, 173 USPQ 685 (CCPA 1972). The guidance that has been provided by court on this matter is

[i]f the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

See In re Thorpe, 777 F.2d 695, 227 USPQ 964, 966 (Fed. Cir. 1985). When applicant=s and prior art=s products are to be identical or substantially identical, the burden shifts to applicant to provide evidence that the prior art product does not inherently possess the claimed properties. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977); In re Fessmann, 489 F.2d 742, 745 180 USPQ 324, 326 (CCPA 1974); and In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980).

With respect to the Cu-Al-Mn alloy composition, Tabei discloses the shape memory alloy (col. 1, lines 55-66) and thermal mechanical treatment (col. 3, lines 52-58) in the same field of endeavor or the analogous metallurgical art. Therefore, it would have been obvious to one having ordinary skill in the art of the cited references at the time the invention was made to provide Palermo with shape memory alloy as taught by Tabei for its intended properties. It has been held that combining known ingredients having known functions, to provide a composition having the additive effect of each of the known functions is within the realm of performance of ordinary skill artisan. In re Castner, 186 USPQ 213 (217). The use of conventional materials to perform their known functions in a conventional process is obvious. In re Raner, 134 USPQ 343 (CCPA 1962).

### ***Response to Arguments***

Applicant's arguments filed January 16, 2004 have been fully considered but they are not persuasive.

Applicants argue that Palermo fails to disclose guide wire continuously or stepwise decreases rigidity from body portion to tip end portion of guidewire. But, applicants' attention is directed to Palermo in col. 1, line 60 to col. 2, line 30, which discloses it is known in the art of cited references that tapered (reads on continuously) wire allows great flexibility at the tip end portion. Furthermore, in col. 2, lines 16-30, it is clearly disclosed that it is conventional for guidewire to have high rigidity body and flexible end portion (reads on stepwise).

Applicants argue that Palermo fails to disclose claimed wire composition. But, applicants' argument against the references individually, one cannot show

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nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue that the body portion of Palermo's guidewire is not significantly more rigid than tip portion. But, instant claims recite rigidity in merely relative terms. None of the instant claims recites any numerical properties' values. Moreover, Tabei has taught the claimed wire material.

Applicants' argument with respect to Tabei is noted. But, Tabei is cited to show the claimed wire material is old and conventional.

Applicants argue that Palermo fails to disclose the wire hardness and rigidity at the body portion. Assuming *arguendo* applicants' argument is correct, but applicants' argument is immaterial because none of instant claims cites hardness and rigidity in a definite measurable numerical values.

Applicants argue that the guidewire tensile strength and rigidity at the body portion of Palermo is poor. But, instant claims do not require tensile strength and define rigidity in relative terms.

## **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant is reminded that when amendment and/or revision is required, applicant should therefore specifically point out the support for any amendments made to the disclosure. See 37 C.F.R. § 1.121.


#### Examiner Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Ip whose telephone number is (571) 272-1241. The examiner can normally be reached on Monday to Friday from 5:30 A.M. to 2:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Roy V. King, can be reached on (571)-272-1244.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SIKYIN IP  
PRIMARY EXAMINER  
ART UNIT 1742

S. Ip  
April 19, 2004